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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,221	03/07/2001	Paul Sanberg	C14-135	5403

7590

07/11/2002

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PATENT, TRADEMARK AND COPYRIGHT MATTERS
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NEW YORK, NY 10017

EXAMINER

BAKER, ANNE MARIE

ART.UNIT	PAPER NUMBER
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1632

DATE MAILED: 07/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/801,221

Applicant(s)

SANBERG ET AL.

Examiner

Anne-Marie Baker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on ____.

2a) ☐ This action is FINAL.

2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-69 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) ☐ Claim(s) ____ is/are allowed.

6) ☐ Claim(s) ____ is/are rejected.

7) ☐ Claim(s) ____ is/are objected to.

8) ☒ Claim(s) 1-69 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.

4) ☐ Interview Summary (PTO-413) Paper No(s). ____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other:

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DETAILED ACTION

The preliminary amendment filed March 28, 2001 (Paper No. 8) has been entered.

Claims 1-69 are pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20 and 43-61, drawn to neural cells, a method of producing neural cells, and cell compositions, classified in class 435, subclass 325.
- II. Claims 21-42, 62-69, drawn to a method of treating Parkinson's disease, classified in class 424, subclass 93.1.
- III. Claims 21-42 and 62-69, drawn to a method of treating Alzheimer's disease, classified in class 424, subclass 93.1.
- IV. Claims 21-42 and 62-69, drawn to a method of treating Huntington's disease, classified in class 424, subclass 93.1.
- V. Claims 21-42 and 62-69, drawn to a method of treating amyotrophic lateral sclerosis, classified in class 424, subclass 93.1.
- VI. Claims 21-42 and 62-69, drawn to a method of treating multiple sclerosis, classified in class 424, subclass 93.1.
- VII. Claims 21-42 and 62-69, drawn to a method of treating Tay Sach's disease, classified in class 424, subclass 93.1.
- VIII. Claims 21-42 and 62-69, drawn to a method of treating Rett Syndrome, classified in class 424, subclass 93.1.

- IX. Claims 21-42 and 62-69, drawn to a method of treating lysosomal storage disease, classified in class 424, subclass 93.1.
- X. Claims 21-42 and 62-69, drawn to a method of treating ischemia, classified in class 424, subclass 93.1.
- XI. Claims 21-42 and 62-69, drawn to a method of treating spinal cord damage, classified in class 424, subclass 93.1.
- XII. Claims 21-42 and 62-69, drawn to a method of treating ataxia, classified in class 424, subclass 93.1.
- XIII. Claims 21-42 and 62-69, drawn to a method of treating amyotrophic lateral sclerosis, classified in class 424, subclass 93.1.
- XIV. Claims 21-42 and 62-69, drawn to a method of treating schizophrenia, classified in class 424, subclass 93.1.
- XV. Claims 21-42 and 62-69, drawn to a method of treating autism, classified in class 424, subclass 93.1.

Claims 21-42 and 62-69 embrace the inventions of Groups II-XV. Should any one of Groups II-XV be elected, Claims 21-42 and 62-69 will be examined only to the extent that they encompass the elected subject matter.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and inventions II-XV are patentably distinct, one from the other, because the inventions are drawn to distinct compositions and materially different methods. The method of the invention of Group I requires different starting materials, different modes of operation, and produce different effects from the methods of the inventions of Groups II-XV. Furthermore, although the cell

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compositions can be used in methods of transplantation to treat Parkinson's disease, as in the method of the invention of Group II, their use is not limited to methods of transplantation, as they can also be used in cell culture to study the effect of various agents on their *in vitro* differentiation or function. Thus, the methods and compositions of the invention of Group I are patentably distinct from the methods of the inventions of Groups II-XV.

Inventions II-XV are patentably distinct, one from the other, because the inventions are drawn to methods that are directed to treating different diseases or conditions and thereby produce different effects. The specification teaches that the claimed method of transplantation can be used to treat the following diseases or conditions: Parkinson's disease, Alzheimer's disease, Huntington's disease, amyotrophic lateral sclerosis, multiple sclerosis, Tay Sach's disease, Rett Syndrome, lysosomal storage disease, ischemia, spinal cord damage, ataxia, alcoholism, schizophrenia, and autism. However, the etiology, clinical course, and treatment protocols differ substantially for each of these diseases or disorders. The methods are not obvious, one over the other, even when the method steps are identical, because the methods steps are being carried out using a different patient population having a substantially different disease or condition. Thus, a method of treating Parkinson's disease would not be obvious as a method for treating head trauma, due to the known differences in etiology and necessary treatment effects that are being sought. Thus, the methods of the inventions of Groups II-XV are patentably distinct, each from the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Anne-Marie Baker, Ph.D.

Anne-Marie Baker
ANNE-MARIE BAKER
PATENT EXAMINER